國立成功大學

110學年度碩士班招生考試試題

編　號：284

系　所：臨床藥學與藥物科技研究所

科　目：藥劑學

日　期：0203

節　次：第 1 節

備　註：不可使用計算機

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※ 考生請注意：本試題不可使用計算機。　請於答案卷(卡)作答，於本試題紙上作答者，不予計分。

1. Explain the following terminology/equation and their applications in pharmaceutics. (16%)
   (1) Q_{10}
   (2) Triangular phase diagram
   (3) Higuchi equation
   (4) Young's equation

2. Please elaborate, according to Good Manufacturing Practices, how to minimize the risk of microbial, particulate and pyrogen contamination in the manufacturing process of sterile products? (15%)

3. List three commonly-used stabilizing agents in the formulations of biological products, and explain their effect. (9%)

4. Describe the factors that influence the physical stability of suspensions, and how to improve it by formulation. (10%)

5. What is the Biopharmaceutical Classification System (BCS)? How do you determine the BCS classification of a drug? (14%)

6. The volume of distribution of a lipophilic drug X is about 300 L. For each of the following statements, indicate whether it is consistent with this observation or not. If not or ambiguous, provide an explanation for it. (12%)
   (1) Plasma protein binding is more pronounced than tissue binding.
   (2) Tissue binding is more pronounced than plasma protein binding.
   (3) The distribution of drug X is more likely to be permeability-rate limited.
   (4) Drug X can not be an acid or base as it is able to cross membranes.
   (5) The clearance of drug X has to be high.
   (6) The half-life of drug X has to be long.

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7. The following pharmacokinetic parameters were reported for a drug Y:
   Oral bioavailability (F)- 0.56;
   Fraction excreted unchanged in urine (fe)- 0.2;
   Unbound fraction in plasma (fu)- 0.3;
   Volume of distribution (Vd)- 0.8 L/Kg;
   Elimination half-life ($t_{1/2}$)- 1.39 hr.
   A patient (40 years old, 70 kg, GFR 100 mL/min) was prescribed 300 mg oral dose of drug Y every 6 hr for a week.
   (1) Calculate the total body clearance (CL) of the drug in this patient. (4%)
   (2) Calculate the renal clearance (CLr). (4%)
   (3) What is the probable mechanism for renal elimination of this drug? (4%)
   (4) Estimate the average steady-state plasma drug concentration for this patient. (4%)

8. Select the plots that agree with linear pharmacokinetics. (8%)
   AUC: Area under concentration-time curve; CL: Total body clearance; K: Elimination rate constant; Vd: Volume of distribution.